K984129

DEC 1 1998

7.0 PREMARKET NOTIFICATION 510(K) SUMMARY

Applicant:	Laura A. Worfolk, Ph.D. Pacific Hemostasis 11515 Vanstory Drive Huntersville, NC 28078 (704) 948-3276
Contact Person:	Mark Ellis, Regulatory Manager, phone #(704) 948-3279 Fax # (704) 875-2092
Date:	November 12, 1998
Trade Name:	Coagulation Control Level 1 (Normal)
Common Name:	Normal Coagulation Control
Classification Name:	Plasma, Coagulation Control (per 21 CFR section 864.5425)
Equivalent Device:	Dade Ci-Trol Coagulation Control Level 1, a pre-amendment device

Description of Coagulation Control Level 1 (Normal)

Pacific Hemostasis Coagulation Control Level 1 (Normal) is a lyophilized preparation of citrated plasma obtained from healthy donors. Stabilizers and buffers have been added to the plasma prior to lyophilization. Each unit of source material used in the preparation of the reagent has been tested by an FDA approved method and found non-reactive for HBsAG and negative for antibodies to HIV and HCV.

Intended Use of Coagulation Control Level 1 (Normal)

Pacific Hemostasis Coagulation Control Level 1 is intended for use as a control to monitor the performance of routine coagulation assays, i.e. Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT) and Fibrinogen assays. It will yield PT, APTT and Fibrinogen values in the normal range.

Summary of Performance Data for Substantial Equivalence Comparisons

Between-run and within-run precision studies yielded substantially equivalent data for Pacific Hemostasis and Dade Brand Coagulation Controls Level 1(I) (Table 1). For both controls a CV of less than 2.0% was obtained for PT and APTT between-run testing. The average CV's obtained for within-run precision were less than 1.5% for PT testing, and less than 1.0% for APTT testing of both products. Fibrinogen testing yielded values of 287 and 268 mg/dL for Pacific Hemostasis and Dade brands, respectively, which are both in the normal range for fibrinogen.

	510(K) Summary Table 1. Data Summary			
	Prothrombin Time Testing		Activated Partial Thromboplastin Time Testing	
	PH	Dade	PH	Dade
Between-run Precision (20 duplicate measurements over a 10 day period)	mean = 12.9 SD = 0.16 CV% = 1.22	mean = 14.1 SD = 0.20 CV% = 1.39	mean = 25.7 SD = 0.20 CV% = 0.79	mean = 26.7 SD = 0.40 CV% = 1.52
Within-run Precision (3 runs of 20 duplicate measurements, average %CV shown.)	1.39	1.20	0.70	0.70

Conclusion

Pacific Hemostasis and Dade brand Coagulation Control Level 1(I) have the same intended use, as normal controls for routine coagulation assays. Both are preparations of citrated plasma obtained from normal donors with added stabilizers and buffers. The performance data presented here, as well as the indistinguishable intended use and technological characteristics support the substantial equivalence claim for Pacific Hemostasis Coagulation Control Level 1 to Dade Ci-Trol Coagulation Control Level I. *Based on the data provided, it is our conclusion that these two products are substantially equivalent.*

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT
[As required by 21 CFR 807.87(j)]

I certify that, in my capacity as a Research Scientist at Pacific Hemostasis, a Fisher Scientific Company, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Laura A. Worfolk

Laura A. Worfolk, Ph.D.

11/12/98

K984129

(Premarket Notification [510(k)] Number)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 1998

Mark Ellis
Regulatory Manager
Pacific Hemostasis
11515 Vanstory Drive
Huntersville, NC 28078

Re: K984129
Trade Name: Coagulation Control Level 1 (Normal)
Regulatory Class: II
Product Code: GIZ
Dated: November 16, 1998
Received: November 18, 1998

Dear Mr. Ellis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

Pacific Hemostasis Coagulation Control Normal, Level 1, is intended for use as a control to monitor the performance of three routine coagulation assays: Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), and fibrinogen concentration in the normal range.

Prescription ✓

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984129